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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA SOUTHERN DIVISION

LINDA A. GALLUPS,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	CIVIL ACTION NUMBER
	)	2:09-cv-00842-WMA
WYETH, INC., et al.,	)	
	)	
Defendants.	)	

REPORT OF PARTIES' PLANNING MEETING AND JOINT DISCOVERY PLAN

Pursuant to Fed.R.Civ.P. 26(f), a meeting was held on July 6, 2009 and attended by: Kristine K. Kraft and Elizabeth Wilkins on behalf of the plaintiff and Maibeth J. Porter, on behalf of Defendants Wyeth, Inc., on its on behalf and on behalf of its unincorporated division Wyeth Pharmaceuticals, and Amgen Inc., Amgen USA, and Immunex Corporation and Lauren Schultz Colton on behalf of Defendants, Amgen Inc., Amgen USA, and Immunex Corporation. Counsel had subsequent discussions on July 14, 2009. Pursuant to Rule 26(f), the parties jointly submit the following discovery plan:

1. **Pre-Discovery Disclosures.** The parties agree to exchange the documents and information referenced by Federal Rule of Civil Procedure 26(a)(1) on or before **July 27, 2009**.

2. **HIPAA Authorizations.** On or before **July 27, 2009**, Plaintiff will provide a fully executed copy of the HIPAA authorization provided to her by Defendants to enable Defendants to obtain copies of plaintiff's protected health information consisting of medical, radiological, and billing records only (and will not permit communications with defense counsel related to the care and treatment of plaintiff or any other matters, except for communications relating to logistics for gathering records and depositions). Defendants also ask the Court to enter a Qualified HIPAA Protective Order in the form attached hereto as Appendix I.

3. **Preservation of Evidence by Defendants.** Defendants represent that Enbrel® hold orders are in place currently to preserve evidence that may be relevant to the claims in this litigation.

4. **Discovery Plan.** This product liability action involves a biological product known as Enbrel®, which has been approved by the United States Food and Drug Administration ("FDA") for the treatment of various autoimmune diseases, including psoriasis, a condition from which plaintiff Linda Gallups suffers. In or about March 2006, plaintiff was prescribed Enbrel® to treat and manage her condition. Plaintiff alleges that her use of Enbrel® caused her to develop side effects, including meningitis and sepsis, leading to septic shock,

mitral valve endocarditis, a cerebrovascular event (stroke), coronary artery disease, and respiratory failure, and congestive heart failure. Plaintiff further alleges that Defendants did not adequately warn about these conditions and suppressed information related to the risks of developing these conditions in either the Enbrel® package insert, the promotional literature distributed to physicians and potential consumers, and/or television advertisements or other materials distributed by Defendants. As a result of these alleged injuries, plaintiff asserts claims against the Defendants for defective design and failure to warn under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD"), and for common law negligence and fraud. Id. ¶¶ 28-51. Plaintiff also seeks punitive damages under each of these legal theories. Defendants deny plaintiff's allegations and maintain that Plaintiff will not be able to prevail on her claims because she will not be able to establish the requisite causation. As an initial matter, there is no scientifically reliable evidence to support a causal connection between the alleged injuries and Enbrel®. And, Defendants contend that issues entirely unrelated to Enbrel® are more likely causes of Plaintiff's alleged injuries. Defendants also maintain that Plaintiff's claims are barred by the learned intermediary doctrine because

Enbrel®'s package insert, at all relevant times, expressly warned that the Plaintiff's alleged injuries were potential side effects associated with the biologic.

Because of the significant causation hurdles Defendants believe Plaintiff faces, Defendants request that the Court enter a bifurcated discovery schedule – the first part of which will relate solely to the issue of medical causation and the second part of which will relate to any remaining legal claims of the case. Defendants incorporate by reference herein their Motion to Bifurcate Discovery.

Plaintiff objects to a bifurcated discovery schedule and process in its entirety. Plaintiff objects to conducting discovery in phases and objects to limiting discovery to certain issues and reserves the right to detail her objections in an Opposition to Defendants' Motion to Bifurcate Discovery. Instead, Plaintiff requests the Court to permit discovery to proceed on all claims simultaneously as described in Section 5 immediately below.

5. Plaintiff's Proposed Discovery Schedule

The period for conducting fact witness discovery on all issues with close on **May 31, 2010**.

Plaintiff shall disclose expert witnesses and submit Rule 26(a)(2)(B) reports by **July 29, 2010**. Plaintiff shall make expert witnesses available for deposition by **September 30, 2010.**

Defendants shall disclose expert witnesses and submit Rule 26(a)(2)(B) reports by **November 15, 2010**. Defendants shall make expert witnesses available for deposition by **January 15, 2011**.

Plaintiff proposes expansion of the limitation for interrogatories and requests for production of documents that Plaintiff may serve on Defendants because of the complexity of this litigation. Plaintiff contends that discovery can more efficiently be managed in this case by permitting Plaintiff to serve initial interrogatories on Defendants totaling 50. Plaintiff proposes that no limitation as to the number of document requests, as is consistent with the Federal Rules of Civil Procedure, apply to either party. Plaintiff further requests the ability to seek leave to serve additional written discovery and to serve such discovery only upon the entry of an Order finding *good cause* for such discovery.

Plaintiff requests that Defendants produce responsive non-privileged documents on a rolling basis of every 30 days, beginning 30 days after the requests for production of documents have been answered.

Plaintiff requests that the limitations of twenty-five (25) interrogatories set forth in Fed. R. Civ. P. 33(a) shall apply as to the interrogatories served by Defendants on Plaintiff.

Plaintiff requests that the deadline for joinder of additional parties and amendment of pleadings be set 30 days after defendants have completed the production of documents.

6. Defendant's Proposed Discovery Plan

As noted above, Defendants propose a bi-furcated discovery plan which will enable the Court to determine, as a threshold matter, whether Plaintiff can establish the requisite medical causation before the parties engage in the time and expense of full discovery. If the Court determines that plaintiff cannot meet her burden of proving that her injuries were proximately caused by Enbrel®, then this case will not proceed to the second stage of discovery:

a. Discovery Relating to Medical Causation

i. The period for conducting discovery, including expert discovery, related to the issue of medical causation will close on **February 5, 2010**.

ii. Written Discovery

Defendants maintain that the Plaintiff's request that the Court expand the limitations on written discovery in this case to fifty (50) interrogatories for plaintiff to send to defendants and unlimited document requests invites abuse and imprecision, and precipitates discovery disputes. Further, Plaintiff's suggestion that she be permitted to propound double the number of interrogatories to defendants than defendants can serve on her is unjust and unnecessary. As such, Defendants propose the following limitations on written discovery during the medical causation stage of discovery:

A. Maximum of 20 interrogatories by each party to any other party related to issues of medical causation.

B. Maximum of 15 requests for production by each party to any other party related to issues of medical causation. Defendants agree to produce responsive non-privileged documents on a rolling basis beginning 30 days after responding to said requests for production.

C. Maximum of 10 requests for admission by each party to any other party related to issues of medical causation.

iii. Depositions during the medical causation period of litigation will be limited to plaintiff's treating physicians, plaintiff's proposed experts, defendants' proposed experts, and a Rule 30(b)(6) deposition of defendants' representatives.

iv. Reports from retained experts on medical causation under Fed.R.Civ.P. (26)(a)(2) will be due:

From plaintiff by **November 6, 2009** (90 days before the close of medical causation discovery). Plaintiff will make her experts available for deposition within 30 days of providing the reports.

From defendants by **January 6, 2010** (30 days before the close of medical causation discovery). Defendants will make their experts available for deposition within 30 days of providing the reports.

b. Medical Causation Briefing and Hearing Schedule

i. Defendants' motion for summary judgment and/or *Daubert* motion based on lack of medical causation evidence will be filed no later than **March 15, 2010**.

ii. Plaintiff's response to defendants' motion(s) based on lack of medical causation evidence will be due 30 days from the service of the motion(s).

iii. Defendants' reply will be due 15 days from the service of plaintiff's response to the motion(s).

iv. Issue of medical causation will be ready for oral argument and submission to the Court after **April 30, 2010**.

c. Discovery Relating to the Plaintiff's Remaining Legal Claims

i. The period for conducting discovery related to the remaining legal claims in the case will close on **January 3, 2011.**

ii. Written Discovery

A. Maximum of 20 interrogatories by each party to any other party related to the remaining claims in the case.

B. Maximum of 15 requests for production by each party to any other party related to the remaining claims in the case. Defendants agree to produce responsive non-privileged documents on a rolling basis beginning 30 days after responding to said requests for production.

C. Maximum of 10 requests for admission by each party to any other party related to the remaining claims in the case.

iii. Depositions will be limited to 7 per side.

iv. Reports from retained experts, other than medical causation experts, under Fed.R.Civ.P. (26)(a)(2) will be due:

A. from plaintiff by **October 4, 2010** (90 days before the close of general discovery). Plaintiff will make his experts available for deposition within 30 days of providing the reports.

B. from defendants by **December 1, 2010** (30 days before the close of general discovery). Defendants will make their experts available for deposition within 30 days of providing the reports.

v. Supplementations under Fed.R.Civ.P. 26(e) due no later than **December 1, 2010** (30 days before the close of general discovery).

d. Miscellaneous Deadlines

i. Plaintiff should be allowed until **September 1, 2010** to join additional parties and to amend the pleadings.

ii. Defendants should be allowed until **October 1, 2010** to join additional parties and to amend the pleadings.

6. **Production of Documents by Defendants in Electronic Format.** Plaintiff seeks production of all relevant documents pertaining to the issues of liability, causation, and damages on a CD in a searchable word format, with a load application to be specified and agreed upon between the parties. Defendants agree to provide relevant, responsive and non-privileged documents in the requested format to the extent the documents are already in electronic format. Defendants do not agree to OCR documents that are not already in such searchable format.

Defendants propose that during the causation phase of discovery, defendants may produce relevant, responsive, non-privileged documents from the following categories: product approval and labeling information for Enbrel®; physician package inserts for Enbrel®; patient package inserts for Enbrel®; adverse event materials; materials from relevant meetings of the United States Food and Drug Administration's Arthritis Advisory Committee during which Enbrel® was discussed; and medical and scientific literature relating to Enbrel®, TNF-inhibitors, psoriasis and the plaintiff's alleged injuries. Should the case proceed beyond the medical causation stage of discovery, Defendants will produce relevant

and non-privileged documents that are responsive to Plaintiff's discovery requests on the remaining issues in the case.

7. **Issues Upon Which the Parties Agree.**

a. The Court has already approved the parties' Stipulated Protective Order, which addresses issues relating to privilege and protected information, including the procedure for asserting a privilege after production of said material is made as required by Federal Rule 26(f)(3)(C).

b. The Parties do request a conference with the Court before the entry of the scheduling order.

c The Parties request a final pretrial conference 30 days before trial.

d. Final lists of trial evidence under Fed.R.Civ.P. 26(a)(3) should be due pursuant to the terms of the pretrial order.

e. The case should be ready for trial 90 days after the Court has ruled on all dispositive motions.

f. All deadlines herein are without prejudice to the parties' right to file any motions prior to the agreed deadlines.

g. The parties do not believe that alternative dispute resolution is appropriate at this time.

Respectfully Submitted: July 20, 2009.

/s/ Maibeth J. Porter
Maibeth J. Porter
Thomas W. Thagard, III
Attorneys for Defendants Wyeth, Inc., on its own behalf and on behalf of its unincorporated division, Wyeth Pharmaceuticals, Amgen Inc., Amgen USA, and Immunex Corporation.

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